(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 801 958 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
22.10.1997 Bulletin 1997/43

(51) Int. Cl.[6]: **A61N 1/375**

(21) Application number: **97104361.7**

(22) Date of filing: **14.03.1997**

(84) Designated Contracting States:
DE ES FR GB IT NL

(30) Priority: **26.03.1996 SE 9601154**

(71) Applicant: **Pacesetter AB**
171 95 Solna (SE)

(72) Inventor: **Dahlberg, Kenneth**
112 26 Stockholm (SE)

(54) Active implant

(57) The invention relates to an active implant comprising a hermetically sealable capsule consisting of a first part (211) and a second capsule-closing part (260), whereby the capsule is arranged to hold a battery unit and an electronics unit (219), means (217, 218) for electrically connecting the battery to the electronics unit and contacts with associated conductors (290) arranged on the exterior of the capsule for connection to electrodes, the first part (211) and the second part (260) being made of an essentially biocompatible material, a partition wall (212) is arranged to form a first essentially closed space in the first part (230) for the battery unit, and an electrically insulating layer (213), impermeable to battery chemicals, is arranged on the surfaces of the biocompatible material facing the first closed space (230), whereby an additional space (235) is formed for the battery unit (235) between the capsule-closing part (260) and the partition wall (212) plus an encapsulated power source/battery unit devised in a similar manner.

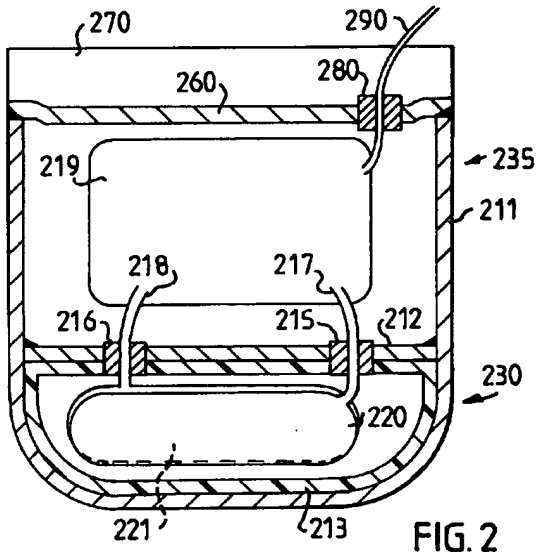

FIG. 2

EP 0 801 958 A1

Description

The invention relates to an active implant, e.g. a pacemaker or defibrillator, containing an electronics unit and an encapsulated battery unit.

Battery unit in this context means essentially all parts of the battery, excluding the casing.

The aforementioned devices are intended for use as implants. The devices can encompass pulse-generating and, possibly, sensing circuits in addition to batteries. These device types are known in the art and used with good results.

There has always been some concern about the effect moisture surrounding the implanted device could have on the device's enclosure, since the device inside the enclosure must be able to operate continuously for a number of years, impervious to surrounding human tissue, for reliable function. In the art, this is achieved by encapsulating the device in a hermetically sealed enclosure, as set forth in e.g. US,A,4 127 134, to prevent damage caused by e.g. increased internal pressure resulting from the emission of gas by the battery during operation.

The aforementioned devices must also be protected from damage inflicted by their electrical components. These components are admittedly essentially inert, but batteries, capacitors etc. constitute potential risks if they are not carefully encapsulated.

US,A,4010759 describes an insulated, corrosion-resistant pacemaker. The electronic components, comprising e.g. a pulse generator, in this pacemaker are enclosed in a titanium capsule which has an essentially continuous insulating layer of Ta_2O_5, serving as an anode, on its exterior. The layer is provided to prevent leakage currents between a tantalum pin on the capsule and the titanium capsule. The battery is arranged outside the titanium capsule, and the entire device is enclosed in a capsule made of a resin-like material. The document states that this design is intended to keep the battery from damaging the electronics.

Insulating the exterior of the case is also known from e.g. US,A,3971388.

US,A,5 144 946 describes e.g. a pacemaker in which a battery and an integral connecting unit are arranged in one part of a two-part case. The said unit comprises electronic components and conductors for interconnecting the battery and the electronic circuits, plus terminals for transmitting signals from the pacemaker to the patient. In one embodiment, the integral connecting unit is enclosed in a capsule made of e.g. silicone rubber, i.e. electrical components are insulated from the battery to protect components from any damage caused by the battery.

One example of the encapsulation of non-inert components, a capacitor in this instance, in the devices according to the above is described in US,A,5 131 388. This document also describes the importance of adapting the size of devices intended for use as implants. The document stipulates the use of a material with good corrosion resistance, such as stainless steel or titanium, for encapsulating the capacitor. However, encapsulation of a conventional, aluminum electrolytic capacitor is involved in this instance.

Another problem to be considered with devices of this kind is the need to array a plurality of components during assembly in a manner which saves space and is satisfactory from the safety point of view.

In the art, it has proved necessary with devices of the above kind, which utilize lithium-iodine batteries, to encapsulate the battery because battery iodine could attack the electronics or external enclosure. However, titanium is not suitable for this enclosure since titanium and even the titanium oxide which forms on it are attacked by iodine. This means that the battery must be encapsulated and kept separated from the external enclosure.

In order to protect devices of the above kind from body fluids and achieve a device which is largely biocompatible, titanium is advantageously used for the external enclosure, since it has proved to be the most biocompatible material.

Battery systems are now available which have proved to be far more compatible with the titanium enclosure. In addition to lithium-iodine batteries there are e.g. batteries containing substances less corrosive than iodine. For example, there is a battery system containing lithium-carbon monofluoride, Li/CF_x in which x is about 1.1. Cells in these systems usually contain a cathode made of a mixture of fluorinated carbon/carbon black plus a binder and an electrolyte, essentially a lithium salt dissolved in an aprotic organic solvent. This system is not damaging to a titanium enclosure in the same way as the lithium-iodine system.

The object of the present invention is to achieve a device of the aforementioned kind which is reliable, i.e. which protects components and which is adapted to the environment in which it is to placed and to the chemicals in the battery unit.

An additional object is to achieve a device which is easy to assemble and seal.

An additional object is to achieve a device of the aforementioned kind with small dimensions.

According to the invention, the above objects are achieved according to the characterizing part of patent claim 1.

Preferred embodiments of the invention are set forth in the sub-claims.

One advantage achieved with the device according to the invention is that the device's external enclosure is electrically neutral, i.e. it will not affect adjacent tissue, a characteristic which can be desirable. Instead, all electrical activity by the implant is conveyed through implanted electrodes.

An additional advantage is that the implant does not require any particular battery system, so other systems, such as lithium-SVO (silver vanadium oxide) or equivalent systems, can be used with the device according to the invention. It should be noted that connection to the

electronics is independent of the battery's construction, since connection between the electronics unit and the battery is via two poles of equivalent design.

The invention will now be described in greater detail, referring to enclosed drawings showing a preferred embodiment.

FIG. 1 shows a schematic cross-section of a bipolar embodiment of the encapsulated battery unit according to the invention.

FIG. 2 shows a schematic cross-section of an active implant containing the battery unit according to the invention.

The encapsulated battery unit shown in FIG. 1 consists of two parts, i.e. a first bowl-shaped part 111 and a second part 112 devised to close the capsule. In this embodiment, the first part 111 and the second part 112 are made of titanium which is, according to the above, a surface material suitable for contact with body tissues. The surface facing the interior of the capsule is given an electrically insulating coating 113, essentially impermeable to battery chemicals such as lithium carbon monofluoride Li/CF_x, which encloses the battery unit and electrically separates the titanium surface from battery chemicals. So the material layer serves as a barrier between e.g. the lithium anode and the titanium surface. The material layer can consist of e.g. polyethylene, halar® film, fluorethene plastic, glass or cermet. The ability to serve as an electrical insulator and impermeability to battery chemicals are the material's most important characteristics.

The second part 112 is welded to the first part 111, whereby a sealed space 130 is formed for the battery unit. Hermetically sealed lead-ins 115, 116 are arranged through the second part 112 for the battery's respective poles 117 and 118.

In the embodiment shown in the FIG. 1, a lithium anode 120 and a cathode 121, whose active material consists of CF_x, are arranged in the sealed space 130. It also holds an electrolyte consisting mainly of a lithium salt dissolved in an aprotic solvent.

When the second part 112, hereinafter referred in regard to Fig. 2 to as a partition wall 212, is arranged in the first bowl-shaped part 111 so it divides up a space in the bottom of the bowl-shaped part, it becomes possible in a second embodiment of the invention to combine the battery unit with an electronics unit in the same enclosure, i.e. in the titanium enclosure, without any additional encapsulation of the battery unit and/or electronics unit, as noted in the description of FIG. 2.

FIG. 2 thus shows an active implant, according to the invention, which has a capsule made of two parts, i.e. a first bowl-shaped part 211 and a second part 260 arranged to close the capsule. And end piece 270 is arranged on the closing second part 260. The first part 211 and the second part 260 are made of titanium, a surface material suitable for contact with body tissues. A partition wall 212 is arranged in the first part 211, essentially parallel to the bottom of the part 211 and divides the part into a space 230 for a battery and a space for an electronics unit 219. The partition wall 212 is preferably made of titanium but could also be made of some other material which is capable of separating the battery space, and the battery enclosed therein, from the electronics unit 219 (not described here) constituting the pacemaker and/or defibrillator, i.e. the active implant, placed in the capsule's second part.

The part of the capsule facing the battery space 230 and the surface of the partition wall facing the battery space is provided with an electrically insulating layer which electrically isolates the battery unit from the titanium surface and electrically insulates the surface from the battery unit while simultaneously serving as a coating 213 which is essentially impermeable to battery chemicals, such as lithium-carbon monofluoride Li/CF_x. The layer of material therefore constitutes a barrier between e.g. the lithium anode and the titanium surface or between battery fluid and the titanium surface. The layer can consist of e.g. polyethylene, halar® film, fluorethene plastic, glass or cermet. The most important characteristics of this material are that it must be an electrical insulator and impermeable to battery chemicals.

The partition wall 212 is sealingly arranged, e.g. welded to the interior of the first part 211 in such a way that a sealed space is created for the battery unit. Hermetically sealed lead-ins 215, 216 are arranged through the partition wall 212 for the battery's respective poles 217, 218. The lead-in 280 is arranged through the closing part 260 next to the end block 270 for conductors to contacts for connection to electrodes.

In the embodiment shown, a lithium anode 220 and a cathode 221, whose active material consists of CF_x, are arranged in the sealed space. An electrolyte, essentially consisting of a lithium salt in an aprotic solvent, is also present.

The above-described embodiments show that a thinner capsule can be achieved for the active implant, since the battery unit, with the implant's enclosure, is an integral unit, and no space is required for an enclosure for a conventional battery/power source. The implant will also contain fewer parts, and reducing the other dimensions of the implant will be possible, since the battery casing is an integral part of the capsule/pacemaker enclosure.

The casing is made of titanium in the described embodiments. Replacing it with some other biocompatible material, such as stainless steel, preferably for the exterior of the enclosure, a cermet, a biocompatible plastic or e.g. perylene or teflon® (tetrafluoroethylene) etc., is also conceivable.

Since the device according to the invention contains fewer parts, production costs will also be reduced.

Devices according to the invention, as described above referring to the embodiments shown in the drawings, can naturally be modified within the scope of the attached patent claims with a view to the description and drawings.

Claims

1. An active implant comprising a hermetically sealable capsule consisting of a first part (211) and a second capsule-closing part (260), whereby the capsule is arranged to hold a battery unit and an electronics unit (219), means (217, 218) for electrically connecting the battery to the electronics unit and contacts with associated conductors (290) arranged on the exterior of the capsule for connection to electrodes, **characterized** in that the first part (211) and the second part (260) are made of an essentially biocompatible material, a partition wall (212) is arranged to form a first essentially closed space in the first part (230) for the battery unit, wherat the partitioning wall (212) and the first part (211) constitutes the casing for the battery unit said casing being an integral part of the capsule and an electrically insulating layer (213), impermeable to battery chemicals, is arranged on the surfaces of the biocompatible material facing the first closed space (230), whereby an additional space (235) is formed for the battery unit (235) between the capsule-closing part (260) and the partition wall (212).

2. An active implant according to claim 1, **characterized** in that the electrically insulating layer (213), which is also impermeable to battery chemicals, is made of one or a plurality of combined materials selected from the group comprising polyethylene, halar® film, fluorethene plastic, glass or cermet.

3. An active implant according to either of claim 1 or 2, **characterized** in that the biocompatible material is titanium.

4. An active implant according to any of claims 1 or 2, **characterized** in that the biocompatible material is a stainless steel whose exterior is coated with e.g. perylene, tetrafluoroethylene (teflon®) or cermet.

5. An active implant according to any of claims 1 to 4, **characterized** in that lead-ins (215, 216) being arranged through the said layer (213) in the partition wall (212) for the battery's respective poles (217, 218).

6. An encapsulated battery unit, **characterized** in that components in the battery unit are enclosed in a hermetically sealable capsule made of a first part (111) and a second, capsule-closing part (112) enclosing a space (130), the first part (111) and the second part (112) are made of a biocompatible material and an electrically insulating layer (113), which is also impermeable to battery chemicals, is arranged on the first part's (111) and second part's (112) surfaces facing the closed space (130).

7. An encapsulated battery unit according to claim 4, **characterized** in that the electrically insulating layer (113), impervious to battery chemicals, is made of one or a plurality of combined materials selected from a group comprising polyethylene, halar® film, fluorethene plastic, glass or cermet.

8. An encapsulated battery unit according to either of claims 6 or 7, **characterized** in that the biocompatible material is titanium.

9. An encapsulated battery unit according to either of claims 6 or 7, **characterized** in that the biocompatible material is a stainless steel whose exterior is coated with e.g. perylene, tetrafluoroethylene (teflon®) or cermet.

10. An encapsulated battery unit according to any of claims 6 to 9, **characterized** in that the first part's (111) insulating layer (113), impermeable to battery chemicals, facing the closed space serves as the enclosure for components in the battery, lead-ins (116, 115) being arranged through the said layer (113) and in the closing part (112) for the battery's poles (117, 118).

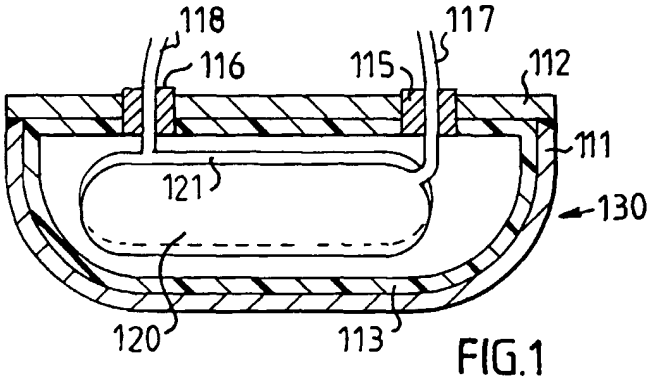
118
116
115
117
112
111
121
130
120
113

FIG.1

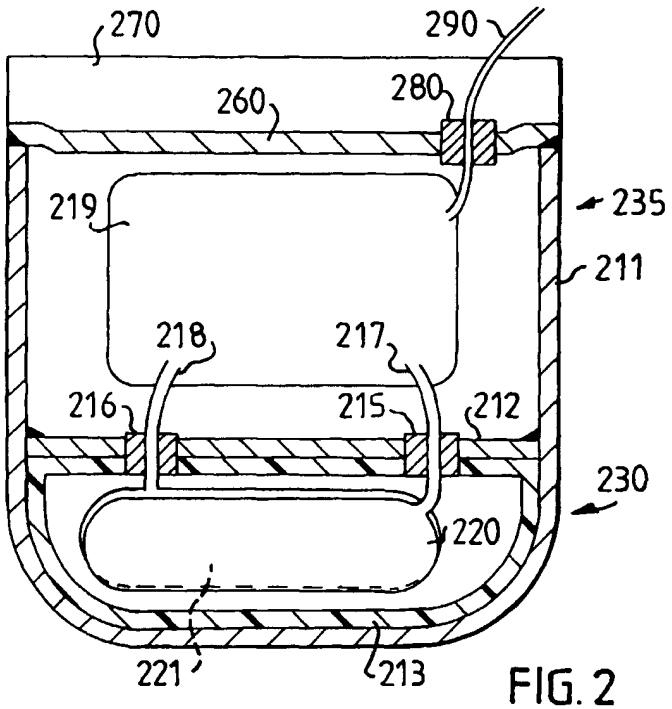
270
290
260
280
219
235
211
218
217
216
215
212
230
220
221
213

FIG. 2

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 97 10 4361.7

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.6)
X	GB 2055296 A (MIECZYSLAW MIROWSKI), 4 March 1981 (04.03.81) * page 1, line 78 - line 93; page 2, line 124 - page 3, line 18, abstract * --	1-10	A61N 1/375
A	US 5131388 A (BENJAMIN D. PLESS ET AL), 21 July 1992 (21.07.92) * column 3, line 53 - line 56; column 4, line 38 - line 40 * -----	1-10	

TECHNICAL FIELDS SEARCHED (Int. Cl.6)

A61N

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
STOCKHOLM	1 July 1997	ANNELI JÖNSSON

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermidiate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P0401)